Complete Summary

GUIDELINE TITLE

Prevention of group B streptococcal infection in newborns.

BIBLIOGRAPHIC SOURCE(S)

Prevention of group B streptococcal infection in newborns: recommendation statement from the Canadian Task Force on Preventive Health Care. CMAJ 2002 Apr 2;166(7):928-30. [25 references] PubMed

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Early-onset group B streptococcal infection in newborns

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Prevention
Screening

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Obstetrics and Gynecology
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To perform a systematic review of the evidence relating to the effectiveness of intrapartum chemoprophylaxis administered to pregnant women in preventing early onset group B streptococcal infection in the newborn
- To identify the best preventive strategy

TARGET POPULATION

Screening

All pregnant Canadian women at 35-37 weeks' gestation

Intrapartum Chemoprophylaxis

Pregnant Canadian women colonized with group B streptococcus and their newborns

INTERVENTIONS AND PRACTICES CONSIDERED

1. Universal screening of pregnant women for group B streptococcal colonization followed by selective intrapartum chemoprophylaxis (intravenous penicillin, clindamycin, or erythromycin) given to colonized women with risk factors
2. Universal screening of pregnant women for group B streptococcal colonization followed by intrapartum chemoprophylaxis given to all colonized women
3. Intrapartum chemoprophylaxis given on the basis of risk factors only

MAJOR OUTCOMES CONSIDERED

Effectiveness of intrapartum chemoprophylaxis on:

- neonatal colonization with group B streptococcus
- early onset group B streptococcal infection in the neonate

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

MEDLINE (December 1966-December 2000), EMBASE (1980-December 2000) and the Cochrane controlled trials register were searched using the following key

words: Streptococcus agalactiae, streptococcal infections, infant-newborn, intrapartum chemoprophylaxis, risk-based strategy, screening. No language restrictions were applied. All comparative and descriptive studies evaluating the effectiveness of intrapartum chemoprophylaxis based on three different strategies were selected. Cited references from retrieved articles were searched for additional studies. Standard neonatal and obstetric textbooks and included reference lists were examined. Abstracts and letters to the editor were excluded. Editorials, indicating expert opinion were reviewed to identify and ensure that no key studies were missed for inclusion in this review.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Quality of evidence was rated according to 5 levels:

I – Evidence from at least 1 properly randomized controlled trial

II-1 – Evidence from well-designed controlled trials without randomization

II-2 – Evidence from well-designed cohort or case-control analytic studies, preferably from more than 1 centre or research group

II-3 – Evidence from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments could also be included here

III – Opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees.

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Quantitative Evidence Review

Data from individual randomized controlled trials or cohort studies were pooled separately using Review Manager to assess the effectiveness of intrapartum chemoprophylaxis for various strategies on neonatal colonization and early onset disease. Due to different study designs, the patient populations, and antibiotic

regimens the results of randomized controlled trials and cohort studies were not pooled. The statistical methods used were relative risk (RR), risk difference (RD), and numbers needed to treat (NNTs), which were derived from the calculated risk difference. Based on the strategy evaluated, the results are expressed either as (a) all colonized women with risk factors who received intrapartum chemoprophylaxis or did not receive intrapartum chemoprophylaxis or (b) as all colonized women who received intrapartum chemoprophylaxis or did not receive intrapartum chemoprophylaxis.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The 8 member Task Force of experts in family medicine, geriatric medicine, paediatrics, psychiatry and epidemiology used an evidence-based method for evaluating the effectiveness of preventive health care interventions. Recommendations were not based on cost-effectiveness of options. Patient preferences were not discussed.

The two lead authors prepared a manuscript providing critical appraisal of the evidence. This included identification and critical appraisal of key studies, and ratings of the quality of this evidence using the Task Force's established methodological hierarchy. The resulting summary of proposed conclusions and recommendations for consideration was presented and deliberated upon in 1- to 2-day meetings from October 1998 to May 1999. Consensus was reached on final recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendations:

A. Good evidence to support the recommendation that the condition be specifically considered in a periodic health examination
B. Fair evidence to support the recommendation that the condition be specifically considered in a periodic health examination
C. Poor evidence regarding inclusion or exclusion of the condition in a periodic health examination, but recommendations may be made on other grounds
D. Fair evidence to support the recommendation that the condition be specifically excluded from consideration in a periodic health examination
E. Good evidence to support the recommendation that the condition be specifically excluded from consideration in a periodic health examination

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

These recommendations were pre-circulated to the members in May 1999 and evidence for this topic was presented by the lead author and deliberated upon in 3 meetings at which the review was presented to the Canadian Task Force in October 1998 and January 1999.

At the meetings, the expert panelists addressed critical issues, clarified ambiguous concepts and analyzed the synthesis of the evidence. At the end of the process, the specific clinical recommendations proposed by the lead authors were discussed, as were issues related to clarification of the recommendations for the clinical application, and any gaps in evidence. The results of this process are reflected in the description of the decision criteria presented with specific recommendations. The final decisions on recommendations were arrived at unanimously by the group and the two lead authors.

Subsequent to the meetings, the two lead authors revised the manuscript accordingly. After final revision, the recommendations were sent by the task force to 2 experts in the field (identified by the task force members at the meeting). Feedback from these experts was incorporated into a subsequent draft of the recommendations. The Task Force reviewed a more final draft of the recommendations in February 2001.

Recommendations from the following organizations regarding prevention of perinatal group B streptococcal diseases were also reviewed: the Society of Obstetricians and Gynecologists of Canada, the Centers for Disease Control and Prevention, and the American Academy of Pediatrics.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Recommendation grade (A-E) and level of evidence (I, II-1, II-2, II-3, III) are indicated with each recommendation. Definitions for these grades and levels are repeated following the recommendations.

- There is fair evidence (level II-1 and II-2) that universal screening for group B streptococcal colonization at 35-37 weeks' gestation followed by selective intrapartum chemoprophylaxis given to colonized women who have risk factors reduces the incidence of colonization and early onset infection in neonates. This appears to be the most efficient strategy (Morales & Lim, 1987; Pylipow, Gaddis, & Kinney, 1994; Gibbs et al., 1994) ([B, II-1, II-2] recommendation).
- There is fair evidence (level II-2) that universal screening for group B streptococcal colonization at 35-37 weeks' gestation followed by intrapartum chemoprophylaxis of all colonized women reduces the incidence of colonization in neonates and prevents early onset neonatal infection, but this

strategy is associated with a much larger proportion of women being treated (Allardice et al., 1982; Garland et al., 1991) ([B, II-2] recommendation).
- There is insufficient evidence to evaluate the effectiveness of intrapartum chemoprophylaxis given on the basis of risk factors alone ([C]).

Collection of antenatal cultures (swab from lower vagina and rectum) should occur at 35-37 weeks' gestation. Swabs should be inoculated into selective broth medium, followed by overnight incubation and then subcultured onto solid blood agar medium. Currently adequate intrapartum chemoprophylaxis consists of at least one dose of intravenous penicillin (5 million units) given at least 4 hours prior to birth. If labour continues beyond 4 hours then penicillin (2.5 million units) should be administered every 4 hours until delivery. Clindamycin 900 mg intravenously every 8 hours or erythromycin 500 mg intravenously every 6 hours until delivery are recommended for women allergic to penicillin. Risk factors include 1) preterm labor (<37 weeks' gestation), 2) prolonged rupture of membranes $\geq$18 hours, 3) maternal fever $\geq$38.0 degrees C, 4) group B streptococcal bacteriuria during pregnancy and 5) previous delivery of a newborn with group B streptococcal disease regardless of current group B streptococcus colonization.

The emerging resistance to erythromycin and clindamycin among group B streptococcal strains is of concern suggesting that the currently recommended antibiotic therapy for women with penicillin allergy may need modification. The increased use of antibiotics in the perinatal period may lead to an increased incidence of bacteria resistant to antibiotics that are currently used as initial therapy for suspected perinatal infections.

Definitions:

Recommendation Grade:

A. Good evidence to support the recommendation that the condition be specifically considered in a periodic health examination
B. Fair evidence to support the recommendation that the condition be specifically considered in a periodic health examination
C. Poor evidence regarding inclusion or exclusion of the condition in a periodic health examination, but recommendations may be made on other grounds
D. Fair evidence to support the recommendation that the condition be specifically excluded from consideration in a periodic health examination
E. Good evidence to support the recommendation that the condition be specifically excluded from consideration in a periodic health examination

Quality of evidence was rated according to 5 levels:

I – Evidence from at least 1 properly randomized controlled trial

II-1 – Evidence from well-designed controlled trials without randomization

II-2 – Evidence from well-designed cohort or case-control analytic studies, preferably from more than 1 centre or research group

II-3 – Evidence from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments could also be included here.

III– Opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Maneuver: Universal screening of pregnant women for group B streptococcal colonization and selective intrapartum chemoprophylaxis to colonized women with risk factors

Level of evidence: Three small cohort studies (Level of evidence II-1, II-2)

Maneuver: Universal screening of pregnant women for group B streptococcal colonization and intrapartum chemoprophylaxis to all colonized women

Level of Evidence: Two cohort studies (II-2)

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Intrapartum chemoprophylaxis is effective in reducing both neonatal colonization and early-onset disease. The most efficient preventive strategy appears to be universal screening of all pregnant women and selective intrapartum chemoprophylaxis of colonized women with risk factors. Universal screening of all pregnant women and intrapartum chemoprophylaxis to all colonized women is also found to be effective.

Subgroups Most Likely to Benefit:

Several maternal factors increase the risk of neonatal group B streptococcal disease: group B streptococcal bacteriuria during pregnancy, gestational age <37 weeks, prolonged rupture of membranes (≥18 hours), maternal intrapartum pyrexia (temperature ≥38 degrees C), and previous delivery of a newborn with group B streptococcal infection.

POTENTIAL HARMS

- Increased incidence of group B streptococcal strains resistant to erythromycin (reported rates ranging from 3.2% to 16.0%) and clindamycin (reported rates ranging from 2.5% to 15%)
- Increased incidence of neonatal sepsis due to ampicillin-resistant organisms other than group B streptococcal infection (possibly related to widespread use of antepartum and intrapartum antibiotics)
- Use of penicillin increases the risk of allergic reactions in women

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Prevention of group B streptococcal infection in newborns: recommendation statement from the Canadian Task Force on Preventive Health Care. CMAJ 2002 Apr 2;166(7):928-30. [25 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2002 Apr 2

GUIDELINE DEVELOPER(S)

Canadian Task Force on Preventive Health Care - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

The Canadian Task Force on Preventive Health Care (CTFPHC) is funded through a partnership between the Provincial and Territorial Ministries of Health and Health Canada.

GUIDELINE COMMITTEE

Canadian Task Force on Preventive Health Care (CTFPHC)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

A complete list of planned reviews, updates and revisions is available under the What's New section at the Canadian Task Force on Preventive Health Care (CTFPHC) Web site.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Canadian Task Force on Preventive Health Care (CTFPHC) Web site.

Print copies: Canadian Task Force on Preventive Health Care, 100 Collip Circle, Suite 117, London, Ontario, Canada, N6G 4X8.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Shah V, Ohlsson, A. Prevention of Early-onset Group B Streptococcal (GBS) Infection in the Newborn: Systematic Review and Recommendations. London (ON): Canadian Task Force, 2001 May. 33 p. (CTFPHC Technical Report #01-6). Available in Portable Document Format (PDF) from the Canadian Task Force on Preventive Health Care (CTFPHC) Web site.
- Stachenko S. Preventive guidelines: their role in clinical prevention and health promotion. London (ON): Canadian Task Force on Preventive Health Care, 1994. Available from the CTFPHC Web site.
- CTFPHC history/methodology. London (ON): Canadian Task Force on Preventive Health Care, 1997. Available from the CTFPHC Web site.
- Quick tables of current recommendations. London (ON): Canadian Task Force on Preventive Health Care, 2000. Available from the CTFPHC Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on September 17, 2002. The information was verified by the guideline developer on September 24, 2002.

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